K013084

SEP 2 7 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

COMPANY AND CONTACT PERSON

Medtronic Perfusion Systems
7611 Northland Drive
Minneapolis, MN 55428
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Marie L. Holm, Associate Product Regulations Manager, Regulatory Affairs

DEVICE NAME

AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface

NAME OF PREDICATED OR LEGALLY MARKETED DEVICE

AFFINITY® 38 μ Arterial Blood Filter (K952532)
AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

DESCRIPTION OF DEVICE

The AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface is a single use device designed to filter microemboli from the blood in the extracorporeal circuits during cardiopulmonary bypass surgery.

The AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface is coated with a non-leaching biopassive surface.

STATEMENT OF INTENDED USE

The AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli.

STATEMENT OF INTENDED USE OF PREDICATED/MARKETED DEVICE

The AFFINITY® 38 μ Arterial Blood Filter is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli.

STATEMENT OF TECHNOLOGICAL CHARACTERISTICS COMPARISON

Information regarding technological characteristics comparison is provided in the following section, "Determination of Substantial Equivalence".

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This **"SPECIAL 510(k)"** is being submitted for a modification to the AFFINITY® 38 μ Arterial Blood Filter. The modification to the current AFFINITY® 38 μ Arterial Blood Filter is to coat the primary blood contact surfaces with Trillium™.

The AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface is being compared to the following Marketed Devices:

- AFFINITY® 38 μ Arterial Blood Filter (K952532)
- AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

The AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface Trillium™ has the same indications statement and intended uses as the:

- AFFINITY® 38 μ Arterial Blood Filter (K952532)

The AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface has "no new technological characteristics (e.g., materials and manufacturing processes)" from the AFFINITY® 38 μ Arterial Blood Filter. The technological characteristic is solely the coating material of the blood pathway:

- Trillium™

The technological characteristic of the Trillium™ Biopassive Surface is common to other medical devices (hollow fiber oxygenators) currently in commercial distribution as follows:

- AFFINITY® Hollow Fiber Oxygenator with Trillium™ Biopassive Surface (K973760)

This technological characteristic "could affect the safety and effectiveness of the device". However, these "technological characteristics do not raise new types of safety or effectiveness questions". In addition, "there are acceptable scientific methods which exist for assessing effects of these new technological characteristics".

"Performance data to assess the effects of these new technological characteristics" has been performed. These "performance data demonstrate" that the AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface is

substantially equivalent to other marketed extracorporeal cardiopulmonary devices.

The biocompatibility and *in vitro* bench testing demonstrated that when compared to the predicate devices, the AFFINITY® 38 μ Arterial Blood Filter with Trillium™ Biopassive Surface does not significantly affect safety and effectiveness and are substantially equivalent to other commercially distributed extracorporeal cardiopulmonary devices. The *in vitro* bench testing included analysis of:

- Coating Characteristics
- Physical Characteristics
- Performance Characteristics

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 7 2001

Ms. Marie L. Holm
Associate Product Regulations Manager
Medtronic Perfusion Systems
7611 Northland Drive N
Minneapolis, MN 55428-1088

Re: K013084
Trade Name: AFFINITY® 38 μ Arterial Filter with Trillium™ Biopassive Surface
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary bypass arterial line blood filter
Regulatory Class: II
Product Code: DTM
Dated: September 11, 2001
Received: September 14, 2001

Dear Ms. Holm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510 (k) Number if known: K013084

Device Name: AFFINITY® 38 μ Arterial Filter with Trillium™ Biopassive Surface

Indications for Use:

The AFFINITY® 38 μ Arterial Filter with Trillium™ Biopassive Surface is indicated for use in cardiopulmonary bypass procedures for the removal of particulate and gaseous microemboli.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013084

Prescription Use ✓ OR Over-The-Counter use ____
(Per 21 CFR 801.109)